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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,685	04/04/2005	Tadayoshi Shiraishi		4435

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Brinks Hofer
Gilson & Lione
PO Box 10395
Chicago, IL 60610

EXAMINER	
O HERN, BRENT T	
ART UNIT	PAPER NUMBER
1794	
MAIL DATE	DELIVERY MODE
04/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,685	SHIRAISHI ET AL.	
	Examiner	Art Unit	
	Brent T. O'Hern	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-21,23 and 24* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 9-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-21,23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims

1. Claims 1-7, 9-21 and 23-24 are pending with claims 23-24 new and claims 1-7 and 9-14 withdrawn.

WITHDRAWN REJECTIONS

2. All rejections of record in the Office Action mailed 7/30/2008 have been withdrawn due to Applicant's amendments in the Paper filed 1/30/2009.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "wherein the ubiquinone supplementation food is a food other than tablets or capsules" in claim 24, lines 2-3 is **new matter** as the disclosure does not have support for said negative limitations.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 15-18 and 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The phrase "not lower than the melting points of ubiquinone" in claim 15, line 4 is vague and indefinite since it is unclear how it is possible for ubiquinone to have more than one melting point.

6. The phrase "wherein the ubiquinone supplementation food is a food other than tablets or capsules" in claim 24, lines 2-3 is vague and indefinite since it is unclear how the ubiquinone supplementation food is a different type of food whether or not it is compressed into a tablet or formed into a capsule. A ubiquinone supplementation is still a food no matter what form it is in. Tablets and capsules are not interpreted as being different types of food but rather different forms of combined food.

Clarification and/or correction is required.

Claim Rejections - 35 USC § 103

7. Claims 15-16, 18 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Udel (US 6,616,942) in view of Ono et al. (US 4,049,831).

Regarding claims 15, 18, and 23-24, Udel ('942) teaches a process for producing a ubiquinone supplementation food which comprises dissolving ubiquinone in an oil/fat under heating, and adding the obtained mixture to a food material *(See col. 3, ll. 7-45. Heating is interpreted as being subject to any heat source including atmospheric and room temperature. The food limitation of claim 18 is nominal and any further limitations with respect to the food produced will possibly make claim 18 subject to a restriction*

requirement. Tablets/capsules of ubiquinone are food.), however, fails to expressly disclose a heating temperature of not lower than the melting points of ubiquinone/(within a range of 50 to 70 °C).

The temperature of the mixture as disclosed in col. 3, l. 18 of Udel ('942) is not the temperature of ubiquinone (Coenzyme Q_{10}) but rather the temperature of the mixture that ubiquinone is combined with. Once the entire mixture has been combined and the product formed the temperature of the product will clearly drop to room temperature, thus, as the process is complete and the product is ready for consumption there is no reason to keep the mixture at said temperature. Udel ('942) expressly discloses the importance of having ubiquinone evenly distributed in the food product and not in the form of unsightful clumps. Thus, in order to provide a uniformly distributed ubiquinone product it would have been obvious to add the ubiquinone as a heated liquid above its' melting point. When ubiquinone is above its melting point it is dispersible and does not have clumps.

Therefore, Udel ('942) is either a liquid, which has been heated or it would have been obvious to heat ubiquinone to the above temperatures in order to provide an aesthetically pleasing product with evenly dispersed ubiquinone.

Regarding claim 16, Udel ('942) teaches the mixture to be added to a food material that is obtainable by dissolving ubiquinone in said oil/fat under heating, and solidifying the resultant *(See col. 3, ll. 7-45 where the ubiquinone dissolves at least to a minimal degree and is preferable over non oil formulations.)*, however, fails to expressly disclose wherein the oil/fat has a melting point of not lower than 20 °C.

However, Udel ('942) teaches adding medium chain triglycerides *(See col. 2, ll. 13-39 and col. 3, ll. 18-40.)*. Medium chain triglycerides are known to be of 6 to 12 carbons in length such as lauric acid, C12:0, which is found in coconut oil with a melting point above 20 °C. Ono ('831) teaches hydrogenated coconut oil, a medium chain triglyceride, having a melting point of 38 °C *(See col. 16, ll. 19-21.)*. It was known to a person having ordinary skill in the art that the melting point of triglycerides can be higher or lower depending on the degree of hydrogenation as required by the user. The fewer the unsaturated bonds the higher the melting point.

Udel ('942) teaches adding wax to the oil as a stabilizer and waxes are known to have higher melting points than liquid oils and known to be present in rice bran and sunflower oils. It is known that fats and oils have various melting points including those similar to waxes due to their degree of saturation and carbon chain length. It is noted that the terms fat and oil are used interchangeably even though oils are generally referred to as liquids at room temperature and fats solids at room temperature. Oils and fats originating from rice, soybeans, canola, tallow, etc. are known to comprise triglycerides with each triglyceride comprising different or the same fatty acids. A liquid oil such as rice, soybean and palm are known to comprise fatty acid chains such as stearic acid, C18:0, which individually if on all three chains or on one or two chains in combination with some other fatty acids such as palmitic, C16:0, or oleic acid, C18:1, are a solid at room temperature. An example of this is palm oil which often is not sold in northern climates during the winter. The colder winter temperatures make it easier for the more solid fractions to freeze, thus making the oil cloudy and precipitating hard fat.

Thus, a liquid oil comprises triglycerides that are fats with melting points above that of the bulk oil. The similar situation exists for most fats which often comprise linolenic, linoleic and oleic acid chains which can provide liquid oil triglycerides within a solid fat composition.

Thus, Udel's ('942) medium chain triglycerides either have the above melting point or it would have been obvious to add a medium chain triglyceride or a fat or oil having a higher melting point to thicken and or stabilize the mixture in a way substantially similar as wax does.

8. Claims 15-18 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Selzer (US 2003/0113307) in view of Udel (US 6,616,942) and Ono et al. (US 4,049,831).

Selzer ('307) teaches a process for producing a ubiquinone supplementation food and a food which comprises dissolving ubiquinone in an oil such as soybean oil which is known to have a melting point that can be lower than 20 °C and adding an emulsifier to form an oil in water emulsion to obtain a nutritious food material *(See paras. 11-25 and 34-41. As discussed above, heating is interpreted as being subject to any heat source including atmospheric and room temperature. The food limitation of claim 18 is nominal and any further limitations with respect to the food produced will possibly make claim 18 subject to a restriction requirement. Tablets and capsules are food.)*, however, fails to expressly disclose a heating temperature of not lower than the melting points of ubiquinone/(within a range of 50 to 70 °C) per claims 15 and 18 or the oil/fat having a melting point not lower than 20 °C per claim 16.

However, Udel ('942) teaches heating the mixture *(See col. 3, ll. 7-45.)* for the purpose of dissolving the oil and other ingredients and keeping the mixture liquid while combining *(See col. 3, ll. 7-45.)*. Medium chain triglycerides are known to be of 6 to 12 carbons in length such as lauric acid, C12:0, which is found in coconut oil with a melting point above 20 °C. Ono ('831) teaches hydrogenated coconut oil, a medium chain triglyceride, having a melting point of 38 °C *(See col. 16, ll. 19-21.)*. It was known to a person having ordinary skill in the art that the melting point of triglycerides can be higher or lower depending on the degree of hydrogenation based on user requirements. The fewer the unsaturated bonds the higher the melting point.

Regarding the melting point of the oil/fat it is known that if the final food product is a solid then it is preferable for the ingredients to also be solid or become solid upon final processing. If the final food is preferred to be a liquid then it is desirable for the ingredients to be liquid or remain or become liquid upon final processing. Thus, since a triglyceride that is a liquid at room temperature or becomes a liquid upon heating have very similar properties it would have been obvious to a person having ordinary skill in the art to select an oil/fat that is a liquid at room temperature for a food that is liquid and selecting an oil/fat that is a solid at room temperature for a food that is a solid.

Therefore, it would have been obvious to a person having ordinary skill in the art at the time Applicant's invention was made to heat Selzer's ('307) mixture as discussed above in order to provide an aesthetically appearing food with ubiquinone.

ANSWERS TO APPLICANT'S ARGUMENTS

9. In response to Applicant's arguments *(See p. 6, para. 2 to p. 7, para. 2 of Applicant's Paper filed 12/9/2008.)* regarding the new limitations for amended claim 15 and new claims 23-24, it is noted that said limitations are discussed above. All 35 USC 102 rejections have been withdrawn.

10. In response to Applicant's arguments *(See p. 7, paras.1- 2 of Applicant's Paper filed 12/9/2008.)* that Udel ('942) does not disclose dissolving ubiquinone, it is firstly noted that the Examiner does not state that it would have been obvious to add ubiquinone that has not been heated. The teachings of Udel ('942) are not limited to dry powder ubiquinone but includes gel capsules. As discussed above, Udel ('942) expressly teaches that ubiquinone gel capsules have the same effectiveness as at least three dry capsules *(See col. 4, ll. 28-44.)*. Thus, if Udel's ('942) ubiquinone were a dry powder then it would not be as effective. Thus, concluding that the ubiquinone in Udel ('942) is powder is beyond the teachings of Udel ('942). It is known to a person having ordinary skill in the art that just because a material in its pure form is a solid at a given temperature (such as room temperature) does not mean that when said material/molecules are mixed with other materials that these materials remain solids. For example, pure triglycerides containing three C18 chains is hard fat, however, when this hard fat is mixed with liquid oil, also containing the same hard fat, at room temperature (well below the melting point of the hard fat) it becomes a liquid. Thus, whether ubiquinone is mixed after heating or mixed without heating, the composition is either the same or substantially the same. If the amount of melted ubiquinone added is

above the saturation value then solid ubiquinone will precipitate out. In a similar way, if the amount of powder ubiquinone is above the saturation point then the excess powder will not dissolve. Furthermore, Udel ('942) does not state that the suspension agent is for powder ubiquinone but rather for "subsequent ingredients" and ubiquinone is not the only ingredient. The suspension agent suspends any precipitated particles that come out of solution when the mixture is cooled, including ubiquinone, even if it was originally added as a liquid.

11. In response to Applicant's arguments *(See p. 6, para. 4, p. 8, para. 1 to p. 9, para. 1 of Applicant's Paper filed 12/9/2008.)* that MCT are not solids with reference to the cited publication, it is noted that hydrogenated coconut oil, an MCT, as discussed above, has melting points above 30 ^{o}C, which clearly makes them solids. Applicant does not set forth whether the C8 and C10 chains as referred to on page 8, paragraph 2 are saturated or unsaturated and what the melting points are for triglycerides with such chains. Applicant's arguments about what is a solid/liquid are lacking a basis temperature which is a key variable that Applicant does not address. Oils and fats can be liquids or solids depending on the temperature of the material.

12. In response to Applicant's arguments *(See p. 8, para. 4 of Applicant's Paper filed 12/9/2008.)* that the wax makes the capsule a slurry, it is noted that said arguments are not commensurate in scope with the claims as the claims do not set forth "slurry" and "solid" limitations.

13. In response to Applicant's arguments *(See p. 9, paras. 2-3 of Applicant's Paper filed 12/9/2008.)* that ordinary food with ubiquinone is different from tablets and capsules with ubiquinone, it is noted that without setting forth any further limitations regarding what ordinary food is there is not any difference as the composition is the same for ubiquinone no matter if it is compressed into a tablet or formed into a capsule or is not formed into a particular structure.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent T. O'Hern whose telephone number is (571)272-0496. The examiner can normally be reached on Monday-Thursday, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Sample can be reached on 571-272-376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BTO/
Brent T. O'Hern
Examiner
Art Unit 1794
April 1, 2009

/Elizabeth M. Cole/
Primary Examiner, Art Unit 1794